

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

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## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) <b>08 MAR 2005</b>		
Applicant's or agent's file reference  2G02.2-084 1	<b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No.  PCT/US04/26760	International filing date (day/month/year)  19 August 2004 (19.08.2004)	Priority date (day/month/year)  20 August 2003 (20.08.2003)
International Patent Classification (IPC) or both national classification and IPC  IPC(7): A61B 17/32 and US Cl.: 606/167, 181, 182, 183		
Applicant  FACET TECHNOLOGIES, LLC		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

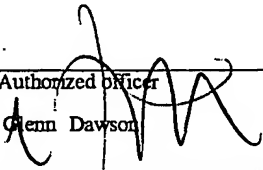
#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Glenn Dawson Telephone No. (703) 308-0858
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**WRITTEN OPINION OF THE  
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**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4-6, 9, 15-17, 19, 21, 22</u>	YES
	Claims <u>1-3, 7, 8, 10-14, 18, 20</u>	NO
Inventive step (IS)	Claims <u>4-6, 9, 15-17, 19, 21, 22</u>	YES
	Claims <u>1-3, 7, 8, 10-14, 18, 20</u>	NO
Industrial applicability (IA)	Claims <u>1-22</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

**V. 2. Citations and Explanations:**

Claims 1-3, 7, 8, 10-14, 18, and 20 lack novelty under PCT Article 33(2) as being anticipated by Schraga 6228100.

As to claims 1-3, Schraga teaches a device for sampling a body fluid, the device comprising a housing and a lancet cartridge (fig. 4), a drive mechanism (fig. 2), the drive mechanism comprising a contact face 26; wherein the contact face of the drive mechanism comprises an angled female recess 26, and the lancet cartridge has at least one complementary angled male profile 76; wherein the housing comprises a resilient portion having a protuberance thereon for engaging at least one recess in the lancet cartridge (fig. 5).

As to claims 7 and 8, Schraga teaches a device for sampling a body fluid, the device comprising a housing and a plurality of lancets, the plurality of lancets 70 being interconnected by a flexible web (fig. 4); and a plurality of alignment tabs 76, each alignment tab associated with a respective one of the plurality of lancets 70, and wherein the housing comprises a channel 26 in which the alignment tabs are received (fig. 4).

As to claims 10 and 11, Schraga teaches a device for sampling a body fluid, the device comprising: a housing (fig. 4) having an arm with a wedge-shaped profile (fig. 6); at least one lancet 70, each lancet having a body portion 75, a sharp tip 74, and an endcap 72; an advancing mechanism (fig. 5) for advancing the at least one lancet into contact with the arm of the housing to drive the wedge-shaped profile between the body portion of the lancet and the endcap, and thereby separate from the body portion of the lancet (col. 4, lines 1-13); and wherein the arm further comprises a ramp (fig. 6).

As to claims 12-14 and 18, Schraga teaches a lancet cassette for removable installation within a sampling device, the lancet cassette comprising a plurality of lancet and a flexible web interconnection the plurality of lancets (fig. 4); wherein the plurality of lancets are arranged in a circular array with sharp lancet tips thereof oriented radially outwardly (fig. 4); a plurality of alignment tabs 76, each alignment tab attached to an inner end of a respective one of the plurality of lancets (fig. 4); a lower face having surface features for engaging an advancing mechanism (fig. 5).

As to claim 20, Schraga teaches a device for sampling a body fluid, the device comprising: an outer housing having first and second portion hingedly connected (fig. 4), an opening 54, and an arm having a wedge-shaped profiled (fig. 6); a lancet cassette, the lancet cassette comprising a plurality of lancets arranged in a circular array (fig. 4), and a flexible web interconnecting the plurality of lancets (fig. 4), each lancet comprising a lancet body 75, a sharp tip 74, and a protective endcap 72, a drive mechanism (fig. 2); and an advancing mechanism (fig. 5) for advancing the at least one lancet into contact with the arm of the housing to drive the wedge-shaped profile between the body portion of the lancet and the endcap, and thereby separate from the body portion of the lancet (col. 4, lines 1-13); and wherein the arm further comprises a ramp (fig. 6).

Claims 1, 7, 12, and 13 novelty under PCT Article 33(2) as being anticipated by Munsch et al. 4794926.

As to claim 1, Munsch et al. teaches a device for sampling a body fluid, the device comprising a housing (11 + 25) and a lancet cartridge (fig. 3); a drive mechanism (fig. 10), the drive mechanism comprising a contact face (tip of 42).

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

As to claim 7, Munsch et al. teaches a device for sampling a body fluid, the device comprising a housing (11 + 25) and a plurality of lancets (fig. 3), the plurality of lancets being interconnected by a flexible web (fig. 3).

As to claims 12 and 13, Munsch et al. teaches a lancet cassette for removable installation within a sampling device, the lancet cassette comprising a plurality of lancet and a flexible web interconnection the plurality of lancets (fig. 3); wherein the plurality of lancets are arranged in a circular array with sharp lancet tips thereof oriented radially outwardly (fig. 3).

Claims 4-6, 9, 15-17, 19, 21, and 22 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a device for sampling a body fluid, the device comprising: a dampening fin; a pair of flanges position on opposite sides of an opening, the flanges having inwardly inclined faces for guiding a lancet along a lancing path; a housing comprising an internal shelf and a lancet cartridge comprising at least one hook; a channel comprising a ring-shaped channel portion and an extension channel portion extending radially from the ring-shaped channel portion; the lancet cassette comprising a well for receiving and retaining an endcap out of a path of travel of the lancet; and the lancet cassette comprising an outer circumferential rim having a plurality of detents formed therein for indexing engagement with a cooperation protuberance of the sampling device.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus meets industrial applicability because the subject matter claimed can be made or used in industry.